

## **RESPONSE TO OFFICE ACTION**

### **A. Status of the Claims**

The Action indicates that claims 8-11, and 16-22 are pending however Applicant notes that claim 22 was canceled in the Response dated May 19, 2004. Claims 8, 16 and 19 are amended herein, and claims 10, 18 and 21 have been canceled. Therefore, claims 8-9, 11, 16-17, and 19-20 are currently active in the application.

Support for amendments to claims 8, 16 and 19 can be found, at least on page 59 lines 6-8.

### **B. Rejection of Claims Under 35 U.S.C. §112, Second Paragraph**

The Action rejects claims 8-11 and 16-18 as being indefinite for failing to point out and distinctly claim the subject matter of the invention. Specifically, the Action asserts that the phrase “at-risk populations” has no limiting definition in the specification. Applicant respectfully traverses the rejection and notes “at-risk populations” is defined in the specification on page 75, lines 2 through 8. In view of the foregoing removal of the rejection is respectfully requested.

### **C. Rejection of Claims Under 35 U.S.C. §102(e)**

The Action rejects claims 8, 9, 11, 16, 17, 19, 20, and 22 under 35 U.S.C. §102(e) as anticipated by Sobel (U.S. Patent No. 5,780,021). In response, Applicant observes that Sobel teaches a dose range of 100,000 to 10 million units (column 49, line 26) thus, Sobel can not anticipate the subject claims. Applicant respectfully requests that this rejection be withdrawn.

**D. Rejection of Claims Under 35 U.S.C. §103a**

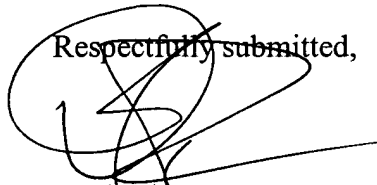
The Action rejects claims 10, 18 and 21 under U.S.C. §103(a) as being unpatentable over Sobel (U.S. Patent No. 5,780,021) in view of Cummings (U.S. Patent No. 5,019,382) and Cummings (U.S. Patent No. 4,497,795). Specifically the Action asserts that Sobel teaches oral administration of IFN- $\alpha$  for the treatment of diabetes, and that in view of Cummings ('382) and Cummings ('795) dosages of about 0.22 to 11 I.U./kg and about 500 to 5000 I.U./kg would be obvious to one of skill in the art.

In response, Applicant observes that the subject claims do not read on Sobel in view of Cummings ('382) and Cummings ('795). Considering the average weight of a human in the United States, about 191 lbs (86.6 kg) for males and 164 lbs (74.5 kg) for females as taught by Ogden *et al.* ("Mean body weight, height, and body mass index, United States 1960-2002," *Advance Data from Vital and Health Statistics*, No. 347 Oct. 27, 2004), a dosage range of about 0.22 to 11 I.U./kg, from Cummings '382, is equivalent to about 19 to 953 I.U./individual for males or 16 to 820 I.U./individual for females. Furthermore, applying the same conversions to the dose range of 500 to 5000 I.U./kg, from Cummins ('795) yields 43,300 to 433,000 I.U./individual for males and 37,300 to 373,000 I.U./individual for females. Thus, none of the dosages taught or fairly suggested by Sobel in view of Cummings ('382) and Cummings ('795) can be used to form a *prima facie* case for obviousness. In light of the foregoing, Applicant respectfully requests that this rejection be withdrawn.

**E. Conclusion**

In conclusion, Applicant submits that, in view of the foregoing remarks, the present case is in condition for allowance and such favorable action is respectfully requested. If however, some unanswered questions remain in the mind of the Examiner, or if the Examiner would be available to discuss the merits of this case, and assist in facilitating its speedy allowance, the Examiner is invited to contact the Applicant's undersigned representative at (512) 536-3055 with any questions, comments or suggestions relating to the referenced patent application.

Respectfully submitted,

A handwritten signature in black ink, appearing to be "David L. Parker", is written over the words "Respectfully submitted,". The signature is stylized with a large loop and a long horizontal stroke extending to the right.

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